

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA

v.

VASCULAR SOLUTIONS, INC.,

and

HOWARD C. ROOT

Defendants.

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CRIMINAL NO. 5:14-CR-00926

**DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT TO  
PRECLUDE CERTAIN PUBLIC STATEMENTS BY THE GOVERNMENT**

Defendants Vascular Solutions, Inc. and Howard C. Root file this Motion and supporting Memorandum for an Order prohibiting lawyers associated with the government from releasing or authorizing the release of any extrajudicial, public statements concerning their opinion as to the guilt or innocence of the defendants, or the merits or evidence in the case.

On October 15, 2015, a senior lawyer from the Department of Health & Human Services, Office of Inspector General (“HHS-OIG”) made certain public statements about the evidence in this case. Specifically, Julie Taitsman, MD, JD, the Chief Medical Officer at HHS-OIG, was the keynote speaker at a medical device conference in Washington, D.C., sponsored by the American Bar Association, the Food & Drug Law Institute, and Medical Device Manufacturers’ Association. According to the conference agenda, her keynote topic was “Discussion of government perspective on medical device enforcement trends and cooperation between industry and government.”<sup>1</sup> During her presentation, Ms. Taitsman said words to the effect of, “Most of you are probably aware of the actions, or as I like to call it, mischief, going on in the Second Circuit. I’m not going to go

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<sup>1</sup> See [www.medicaldevices.org/resource/resmgr/Agendas/ABA\\_Medical\\_Device\\_Agenda\\_20.pdf](http://www.medicaldevices.org/resource/resmgr/Agendas/ABA_Medical_Device_Agenda_20.pdf).

into detail on those shenanigans. I do encourage you all to pay close attention to a case in the Western District of Texas, *United States v. Vascular Solutions*. It's much more favorable to us.”<sup>2</sup> Ms. Taitsman went on to briefly describe the nature of deep and superficial veins, and stated that the Company: did not have clinical support to promote for perforator veins; persisted in off-label marketing even when a clinical trial failed; and had data showing that the product was less safe than a competitor's. She also stated that the case was “hand-picked” by the government because it was such a strong case; and that the government “went on the offensive.” These statements, by a lawyer associated with the government,<sup>3</sup> implicate the local rules of this Court and DOJ and HHS policies and regulations with respect to public comment regarding ongoing cases. Accordingly, defendants request that this Court enter an Order limiting similar extrajudicial statements from the prosecution team and its agents.

### **ARGUMENT**

The Local Rules of this Court provide that after the return of an indictment, “a lawyer associated with the prosecution or defense must not release or authorize the release of any extrajudicial statement, for dissemination by any means of public communication, related to the matter and concerning: . . . any opinion as to the accused's guilt or innocence or as to the merits of the case or the evidence in the case.” W. Dist. Tex. Local Rule No. AT-6(6), Publicity and Trial Management.

Department of Justice regulations likewise strictly limit the release of information by Department personnel relating to ongoing criminal proceedings. *See* 28 C.F.R. § 50.2(a)-(b). These regulations provide that “disclosures should include only incontrovertible, factual matters, and

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<sup>2</sup> To Defendants' knowledge, this conference was not recorded, and there is no transcript available. Defendants report here what has been reported to them by witnesses to Ms. Taitsman's statements.

<sup>3</sup> To Defendants' knowledge, the government attorneys prosecuting this case did not play a role or otherwise condone Ms. Taitsman's comments.

should not include subjective observations,” and that “[s]tatements concerning evidence or argument in the case . . . tend[] to create dangers of prejudice without serving a significant law enforcement function.” *See* 28 C.F.R. §§ 50.2(b)(2)&(6). Recognizing the danger of pre-trial statements about an indicted case, the Department of Justice requires prior approval by the Assistant Attorney General or United States Attorney with respect to “[a]ny public communication by any Department component *or investigative agency or their employees* about pending matters . . . or about pending cases . . . .” *See* U.S. Attorney’s Manual, 1-7.401, Guidance for Press Conferences and Other Media Contacts (emphasis added). Similarly, the Department of Health and Human Services prohibits the dissemination of information pertaining to “pending legal matters.” *See* HHS-OIG Guidelines on the Provision of Information to the News Media, [http://www.hhs.gov/news/media\\_policy.html](http://www.hhs.gov/news/media_policy.html).

The statements by this HHS-OIG lawyer outlined above express an “opinion . . . as to the merits of the case or the evidence in the case.” W. Dist. Tex. Local Rule No. AT-6(6). Moreover, far from “incontrovertible, factual matters,” these statements involved “subjective observations,” and “[s]tatements concerning evidence,” which the government itself concedes “tends to create dangers of prejudice without serving a significant law enforcement function.” *See* 28 C.F.R. §§ 50.2(b)(2)&(6); *see also* Tex. Disciplinary Rule 3.07 (prohibiting extrajudicial statements that “a reasonable person would expect to be disseminated by means of a public communication if the lawyer knows or reasonably should know that it will have a substantial likelihood of materially prejudicing an adjudicatory proceeding”); D.C. Rule Prof. Conduct 3.8(f) (providing that a “lawyer engaged in a case being tried . . . shall not make an extrajudicial statement that the lawyer knows or reasonably should know will be disseminated by means of mass public communication and will create a serious and imminent threat of material prejudice to the proceeding,” particularly “extrajudicial comments which serve to heighten condemnation of the accused”).

**CONCLUSION**

For the reasons stated above, to avoid “creat[ing] dangers of prejudice without serving a significant law enforcement function,” the defendants seek an order prohibiting lawyers associated with the government from releasing or authorizing the release of any extrajudicial, public statements concerning their opinion as to the guilt or innocence of the defendants, the merits of the case, or the evidence in the case.

Dated: October 22, 2015

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I hereby certify that on October 22, 2015, I electronically filed the foregoing motion via the CM/ECF system, which will effectuate service on all counsel of record who are properly registered for CM/ECF service.

s/ Johnny Sutton